



California Medical Association

Physicians dedicated to the health of Californians

August 14, 2014

BY FEDERAL EXPRESS

Honorable Tani G. Cantil-Sakauye, Chief Justice
and Honorable Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, California 94102-4797

*Re: Lewis v. Superior Court (Medical Board of California), No. S219811
(Ct. App. No. B252032; L.A. Super. Ct. No. BS139289)
Amicus Letter Brief of California Medical Association and the American Medical
Association in Support of Petition for Review*

Dear Chief Justice Cantil-Sakauye and Associate Justices:

The California Medical Association (CMA) and the American Medical Association (AMA) submit this letter as *amicus curiae*, pursuant to rule 8.500(g) of the California Rules of Court, in support of the petition for review in the above referenced case of *Lewis v. Superior Court (Medical Board of California)*, 226 Cal. App. 4th 933 (2014).

I. Interests of the California Medical Association and the American Medical Association

CMA is a non-profit, professional association for physicians with approximately 39,000 members throughout the state of California. For more than 150 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA and its physician members are committed to the protection of a patient's right to medical privacy and confidentiality, which is the foundation of the patient-physician relationship and is essential to the ability of a physician to provide quality and effective care.

The AMA is a private, voluntary, nonprofit organization of physicians and medical students. It is the largest such organization in the United States. Additionally, through state and specialty medical societies and other groups seated in its House of Delegates, substantially all U.S. physicians, residents and medical students are represented in the AMA policy making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health. Today, its members practice in all fields of medical specialization and in all states. The AMA submits this letter as a member of the Litigation Center of the American Medical Association and the State Medical Societies (Litigation Center). The Litigation Center was formed in 1995 as a coalition of the AMA and private, voluntary, nonprofit state medical societies to represent the views of organized medicine in the courts. Fifty state medical societies and the Medical Society of the District of Columbia join the AMA as members of the Litigation Center.

Both CMA and the AMA have a strong interest in ensuring that prescription drug monitoring databases such as California's Controlled Substance Utilization Review and Evaluation System (CURES) are governed by strong confidentiality safeguards and the disclosure of patient data to third-party government agencies be subject to clear and consistent regulations and procedures that properly balance patient privacy with the governmental interest.

II. Review Is Warranted

Review of *Lewis* is necessary to settle an important question of law that can have broad negative consequences on patients and the practice of medicine throughout California. Under the California Constitution, patient medical information is entitled to confidentiality and privacy protections that can be breached by the government only when there is a compelling state interest that is met with the least intrusive means.¹ The court in *Lewis* misapplies this law to CURES, a vast government database that collects prescription drug information about patients and their doctors, and opens the door to potentially widespread unjustified government intrusion into sensitive medical information. The care of patients and the ability of physicians to exercise sound medical judgment ultimately may suffer due to the failure of *Lewis* to properly balance the interests of patients and doctors against the government's case.

A. Patients Have an Expectation of Privacy In Their Medical Information and Are Unaware of How Their Sensitive Data in CURES May Be Used By the Government.

The CURES system contains over 100 million entries of controlled substances dispensed in California and is maintained and administered by the Office of the Attorney General in the California Department of Justice (DOJ).² CURES allows physicians and pharmacists to access controlled substance history information necessary to properly evaluate their patients and prevent abuse of controlled substances. Established in 1997, the CURES database has been available to registered health care provider users since 2009.³ In recent years, however, access by regulatory agencies and law enforcement have significantly increased, undermining its role as a tool to ensure safe patient care. In 2013, the California Legislature passed Senate Bill 809 which provided approximately \$1.5 million annually to maintain CURES in addition to funding in the 2013 budget to upgrade the system.⁴ The DOJ recently released a Feasibility Study Report for an upgraded CURES 2.0 system which proposes "increased data collection capabilities and increased analytical tools for investigative purposes."⁵ Further, in 2014, Senate Bill 1258 attempted to expand the individuals who are eligible to be registered users to directly access

¹ CAL. CONST., ART. 1, § 1.

² See CURES/PDMP website, State of California, Department of Justice, Office of the Attorney General, at <http://oag.ca.gov/ures-pdmp> (Last visited July 23, 2014).

³ *Controlled Substance Utilization Review & Evaluation System: Feasibility Study Report*, State of California, Department of Justice, Office of the Attorney General (April 2014) at 1-2, available at http://www.cio.ca.gov/Government/IT_Policy/IT_Projects/pdf/0820%20-%20218_0820%20-%20218%20DOJ%20CURES%20_0%20FSR%20Final.pdf.

⁴ Senate Bill 809, 2013 Stats. Ch. 400.

⁵ *Controlled Substance Utilization Review & Evaluation System: Feasibility Study Report*, *supra* n.3 at 6.

CURES data to include investigators within the Department of Consumer Affairs.⁶ Although Senate Bill 1258 failed to pass out of committee this year, it is indicative of the growing trend of increased access to CURES by non-health care providers for purposes beyond patient care.

Health & Safety Code section 11165 broadly allows the DOJ to provide confidential, identifiable patient prescription data to any "state, local, and federal public agencies for disciplinary, civil or criminal purposes."⁷ Patients and physicians must rely only on the DOJ's discretion as to which government agencies can directly access prescription data in CURES, and where there is a request for data, whether to release the requested information and how much of the data is disclosed. The statute applies not only to regulatory agencies tasked with enforcing the Medical Practice Act and other statutory provisions addressing the prescribing of controlled substances, but to any public agency at the state, local, and federal level, including law enforcement. Unless constitutional limits are imposed, the law permits law enforcement and other government agencies to access confidential prescription records for purposes that do not necessarily further the state's interest in preventing prescription drug abuse and diversion, the primary purpose of CURES, without a warrant, any showing of reasonable cause, restrictions as to the scope of the accessible data, or limits on the discretion of the inspecting officers. While CMA supports CURES as a "valuable preventative, investigative and educational tool for health care providers, regulatory agencies, ... and law enforcement[,]"⁸ the integrity of the system and the privacy of patients demand clear guidelines on the use of CURES data by government agencies to adequately protect patient privacy.

Lewis assumes that since "[t]here is a diminished expectation of privacy in controlled substances prescription records maintained in CURES, ... it does not follow that a patient's expectation of privacy in his or her controlled substances prescription records is the same as the expectation of privacy in medical records."⁹ Patients, however, have a high expectation of privacy in the provision of medical services.¹⁰ Both California's Confidentiality of Medical Information Act (CMIA) and the federal Health Information Portability and Accountability Act of 1996 (HIPAA) define medical information broadly to include any individually identifiable information regarding a person's "medical history, mental or physical condition, or treatment."¹¹ Moreover, Health & Safety section 11165(d) requires dispensing pharmacies to report identifying patient information to CURES including information not only related to the dispensed drug, but diagnostic codes that identify the patient's medical condition.¹² Since many

⁶ Senate Bill 1258 (Amended March 25, 2014).

⁷ Health & Safety Code §11165(c)(2).

⁸ Senate Bill 809, 2013 Stats. Ch. 400.

⁹ *Lewis v. Superior Court (Medical Board of California)*, 226 Cal. App. 4th 933, 2014 WL 2212122 at 8 (2014).

¹⁰ *Tuscon Woman's Clinic v. Eden*, 379 F.3d, 531, 550 (9th Cir. 2004); see also *Board of Medical Quality Assurance v. Gherardini*, 93 Cal.App.3d 669, 678 (1979) ("A person's medical profile is an area of privacy infinitely more intimate, more personal in quality and nature").

¹¹ Civil Code §56.05(j); see also 45 C.F.R. §160.103.

¹² Under Health & Safety section 11165(d), the following information is reported to CURES: patient name, address and date of birth, identifying information for the prescriber and dispensing pharmacy, the National Drug Code number of the dispensed drug, quantity, International Classification of Diseases (ICD) diagnostic code if available,

medications are approved for use to treat specific medical conditions, prescription records reveal sensitive, intimate and potentially stigmatizing details about a patient's health.¹³

Lewis also states that "the CURES statute informs patients ... that controlled substances prescription records are subject to disclosure to the state for electronic monitoring by the Department of Justice. ... Thus, ...[the] patient know[s] who is authorized to receive CURES data and under what narrow circumstances."¹⁴ Even assuming the average patient is familiar with the statutory language of Health & Safety Code section 11165, the statute provides little guidance on which government agencies access or receive CURES data and under what circumstances. Unlike other instances where medical information such as immunization information is reported to the state, patients are not informed by their health care provider that their controlled substances prescription information will be reported to DOJ or how that information may be used or shared by the DOJ.¹⁵

B. Constitutional Limits Must be Imposed Because the CURES Statute Lacks Sufficient Safeguards To Protect Patient Privacy From the Government's Unfettered Access to CURES Data.

In eschewing constitutional limits on the DOJ's ability to share CURES data, the court in *Lewis* summarily states that there are "sufficient safeguards" to protect patient privacy and confidentiality¹⁶ but does not adequately specify any such safeguards. To the contrary, Health & Safety Code section 11165 expressly gives the DOJ limitless discretion as to how it shares CURES data and with which other government agencies. Civil Code section 1798.24(e) is equally broad in that it permits the DOJ to share an individual's personal information "[t]o a person, or to another agency where the transfer is necessary for the transferee agency to perform its constitutional or statutory duties, and the use is compatible with a purpose for which the information was collected[.]"

In addition, the laws that ensure that health care providers properly safeguard the confidentiality of patient information may not be applicable to CURES.¹⁷ Many of California's laws protecting patient privacy and security apply only to health care providers, health plans, or contractors.¹⁸ Similarly, HIPAA only applies to health care providers, health plans and health care clearinghouses that use electronic means to transmit health information.¹⁹ Health care

number of refills, whether the drug was dispensed as a refill or first time request, date the drug was prescribed, and date the prescription was dispensed.

¹³ See *O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) ("Medical information in general, and information about a person's psychiatric health and substance-abuse history in particular, is information of the most intimate kind").

¹⁴ *Lewis*, 226 Cal. App. 4th 933, 2014 WL 2212122 at 11.

¹⁵ See Health & Safety Code §120440(e).

¹⁶ *Lewis*, 226 Cal. App. 4th 933, 2014 WL 2212122 at 1, 9, 10, and 13.

¹⁷ Note that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) does apply to government agencies which act as health plans in their administration of Medicare and Medicaid.

¹⁸ See Civil Code § 56.10 (disclosure of medical information); Health & Safety Code §§123100 *et seq.* (patient access to health records); Health & Safety Code §130203 (safeguards to protect privacy of patient information).

¹⁹ 45 C.F.R. §160.103.

providers are subject to steep civil penalties that can reach millions of dollars and, in some cases, criminal liability for violations of CMIA and HIPAA.²⁰ *Lewis*, however, acknowledges that "there are no penalties in CURES for unwarranted public disclosure"²¹ and the DOJ's position is that these protections in the law do not apply to the DOJ in their maintenance of CURES. In other words, under the CURES statute, DOJ both possesses broad discretion in determining access to and disclosure of CURES information and enjoys impunity over its exercise of that discretion.

C. *Lewis* Can Have Far-Reaching and Long-Lasting Consequences on the Care of Patients and Practice of Medicine.

The duty of physicians to protect patient privacy lies at the very core of the medical profession. Confidentiality is one of the most enduring ethical tenets in the practice of medicine, and is essential to the patient-physician relationship.²² It is the cornerstone of the patient's trust, successful medical information gathering for accurate diagnosis and treatment, an effective physician-patient relationship, good medicine and quality care.²³

Confidentiality is a necessary precondition for any patient to willingly and fully share sensitive personal information with a physician. Patients are routinely asked to disclose private and even embarrassing information to physicians who are entrusted to protect this information from unwarranted disclosures. Only within this trusting relationship can physicians provide effective treatment and preserve the basic human dignity and privacy rights of the patient. Indeed, the very nature of the health care delivery process – which begins with a physician listening to the patient's complaints and concerns, performing physical examinations, and diagnosing the problem – requires the patient to be completely open and candid with the physician in order for the physician to gain an accurate understanding of the patient's medical problem and medical history and determine the best course of treatment. Thus, if patients are not completely open and frank with their health care provider, the result could be the "improper diagnosis and treatment of important health conditions."²⁴

A patient will fully and candidly disclose his or her full medical history only if the patient believes that the physician will assertively guard the privacy of such information. By contrast, if a patient believes that such information cannot or will not be protected, he or she may withhold

²⁰ See Civil Code §56.36; 45 C.F.R. §§160.400 *et seq.*

²¹ *Lewis*, 226 Cal. App. 4th 933, 2014 WL 2212122 at 10.

²² The Hippocratic Oath, an ethical guide of the medical profession since the fifth century B.C., states, "All that may come to my knowledge in the exercise of my profession ... , I will keep secret and will never reveal." DORLAND'S MEDICAL DICTIONARY 609 (26th ed. 1981). See also *Privacy in the Context of Health Care Report 2-I-01*, American Medical Association, Council on Ethical and Judicial Affairs at 2, available at www.ama-assn.org/ama1/pub/upload/mm/369/ceja_2i01.pdf ("Confidentiality is one of the oldest medical ethical precepts, dating back to the Hippocratic Oath").

²³ California Medical Association, *CMA Policy: Medical Privacy Rights*, Resolution HOD 503-99 (1999).

²⁴ Chari J. Young, *Telemedicine: Patient Privacy Rights of Electronic Medical Records*, 66 UMKC. L. REV. 921, 930 (1998).

important facts from the physician.²⁵ Without full disclosure of the patient's symptoms and medical history, physicians may not be able to provide the patient with effective care and advice. Worse, the patient may decline to seek medical care at all, thereby allowing a potentially reversible condition to deteriorate or a communicable disease to go unrecognized and untreated. Thus, maintaining patient privacy is "essential to the effective functioning of the health and public health systems."²⁶

Finally, this case raises a very contemporary issue facing the courts regarding the right to privacy in the digital age. In *United States v. Jones*, 132 S.Ct. 945 (2012), the U.S. Supreme Court found that the warrantless use of a GPS device to track the plaintiff's vehicle violated his reasonable expectation of privacy. In her concurring opinion, Justice Sotomayor addressed how information and history is preserved electronically and can be easily collected, maintained, and mined by the government in mass quantities for years into the future.²⁷ More recently, the Supreme Court unanimously held in *Riley v. California*, 134 S.Ct. 2473 (2014), that while a privacy interest retained by an individual after arrest was significantly diminished, the police must obtain a warrant to search digital information on a cell phone seized from an individual who has been arrested. The Court pointed out that in the past, "a search of a person was limited by physical realities and tended as a general matter to constitute only a narrow intrusion of privacy."²⁸ The "immense storage capacity" of the modern cell phone, however, removes the limitations that come with physical practicability and transforms the possible intrusion on privacy.²⁹ The Court also noted that the ability to digitally collect many distinct types of information can "now reveal much more in combination than any isolated record" and allowing police officers the ability to search cell phone data without a warrant would give them "unbridled discretion to rummage at will among a person's private effects."³⁰ While the Court admitted that its decision will impact "the ability of law enforcement to combat crime," it simply stated that "[p]rivacy comes at a cost."³¹

Similar to the vast amount of personal information stored in GPS devices and cell phones, CURES technology has also greatly increased the quantity and type of information available to government agencies, including the Medical Board and law enforcement. Medical Board investigators already can easily access over 100 million individually identifiable entries of schedule II, III and IV controlled substances dispensed to patients in California³² sitting at their desks. *Lewis* leaves the door open to any other government agency or employee to gain such powerful, unfettered access. Gathering information in CURES is cheaper and easier in comparison to conventional information gathering techniques used in the recent past and enables

²⁵ See *United States v. Chase*, 340 F.3d 978, 990 (9th Cir. 2003) (explaining that candor is essential to the psychotherapist-patient relationship "because patients will be more reluctant to divulge unsavory thoughts or urges" if they know that their information will not be kept confidential and may be disclosed without their consent).

²⁶ Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 490 (1995).

²⁷ *United States v. Jones*, 132 S.Ct. 945, 956 (2012) (Sotomayor, J., concurring).

²⁸ *Riley v. California*, 134 S.Ct. 2473, 2478 (2014).

²⁹ *Id.* at 2489.

³⁰ *Id.*

³¹ *Id.* at 2493.

³² See CURES/PDMP website, *supra* n.2.

the government to quickly correlate and aggregate data from different sources and store immense amounts of data. Records that once revealed only "a few scattered tiles of information about a person now reveal an entire mosaic" of a person's medical history.³³ This allows for the Medical Board and other government agencies to proceed surreptitiously, evading the ordinary checks that constrain abusive government practices that violate patient privacy.³⁴ Such intrusions can discourage patients from fully and candidly disclosing their medical history with physicians or seeking medical care at all and compromise the ability of physicians to provide quality care. Given the recent court decisions protecting the privacy of data in GPS devices and cell phones, prescription records that constitute confidential medical information should be afforded similar protections under the law.

Accordingly, based on the discussion above, CMA urges the Court to grant the petition for review.

Respectfully,

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³³ Memorandum Opinion at 54, *Klayman et al., v. Obama et al.*, No. 13-0851 (D.D.C. December 16, 2013).

³⁴ *Jones*, 132 S.Ct. at 956 (Sotomayor, J., concurring).

PROOF OF SERVICE

*Alwin Lewis, M.D. v. Superior Court of the State of California, County of
Los Angeles (Medical Board of California, Real Party in Interest) -
Case No. S219811*

I, Farah Kader, hereby declare:

I am employed in Sacramento, California. I am over the age of eighteen years and am not a party to the above-entitled action. My business address is 1201 J Street, Sacramento, California 94814.

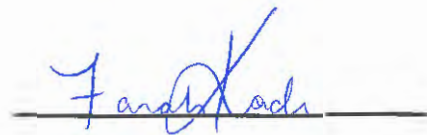
On August 14, 2014, I caused the document(s) to be served as indicated below:

***AMICUS CURIAE* LETTER BRIEF OF THE CALIFORNIA
MEDICAL ASSOCIATION AND THE AMERICAN
MEDICAL ASSOCIATION IN SUPPORT OF PETITION FOR
REVIEW**

- U.S. Mail: By mailing a true copy thereof via first-class postage through the United States Postal Service, as set forth in the attached Service List.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on August 14, 2014, at Sacramento, California.



Farah Kader

SERVICE LIST

*Alwin Lewis, M.D. v. Superior Court of the State of California, County of Los Angeles (Medical Board of California, Real Party in Interest) -
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